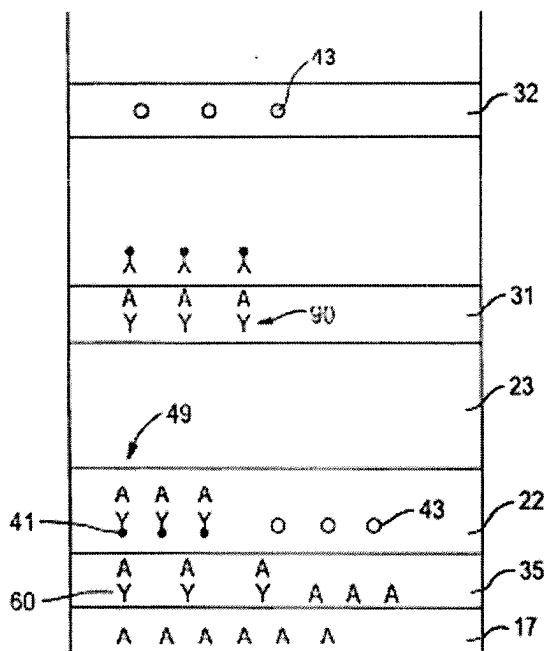


## REMARKS

Claims 2, 5-6, 12, and 37-47, including independent claim 37, are currently pending in the present application. To better understand the nature of the claimed invention, reference is made to an embodiment of the present application shown in Fig. 3, a portion of which is reproduced below.



In this embodiment, a test sample containing an analyte A is initially contacted with a sampling pad 17. At the sampling pad 17, a certain quantity of the analyte A binds to a first capture reagent 60 immobilized at the scavenging zone 35, such as an amount less than or equal to a predefined base quantity of analyte considered "normal" for the particular test sample. From the sampling pad 17, any analyte A in excess of the predefined base quantity travels to the conjugate pad 22, where it mixes with conjugated detection probes 41 and calibration probes 43. The excess analyte A binds with the conjugated detection probes 41 to form analyte/conjugated probe complexes 49. Because the conjugate pad 22 is positioned downstream from the scavenging zone

35, however, it is not necessary to supply detection probes 41 for binding to any of the analyte A that is already captured by the scavenging zone 35. In this manner, the overall amount of required probes is reduced, which provides substantial cost savings. At the detection zone 31, the complexes 49 are captured by a second capture reagent 90. If desired, the first capture reagent 60 at the scavenging zone 35 may be substantially identical to the second capture reagent 90. Thus, should any of the first capture reagent 60 somehow become free from the scavenging zone 35 and travel to the detection zone 31, it will not bind to the second capture reagent 90 and adversely impact the desired reduction in detection sensitivity. Further, the calibration probes 43 travel through the detection zone 31 to bind with a capture reagent (not shown) at the calibration zone 32. Once captured, the signal of the probes at the detection zone 31 and calibration zone 32 may be measured using any known method of detection, such as visually or with a reading device.

In the Office Action, previous independent claim 1 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,509,196 to Brooks, et al. in view of U.S. Patent No. 6,258,548 to Buck. Brooks, et al. describes a membrane strip that includes an application point, a contact region, and a detection zone. The contact region includes test particles and internal control particles. The test particles are coated with a binding agent for the analyte, such as an antibody. The internal control particles are also coated with a binding agent. However, the binding agent of the control particles is not specific for the analyte, such as an antibody that binds to an antigen that is uninvolved in the assay. In Example 1, for instance, the test particles are coated with a mouse monoclonal antibody that is specific for a myoglobin analyte. On the other

hand, the internal control particles are coated with mouse monoclonal antibody MOPC31-c, which has an unknown specificity for myoglobin. According to Brooks, et al., the purpose of using such internal control particles, which are not specific for the analyte, is to determine the amount of “non-specific binding” that occurs during the assay.

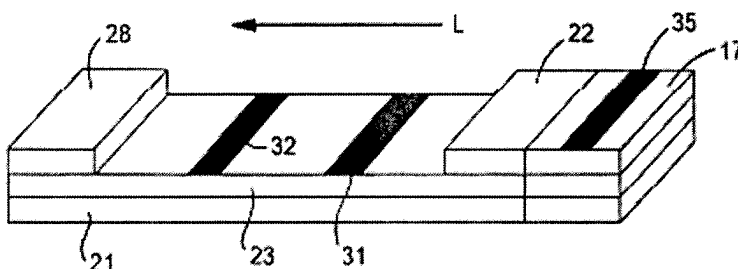
Brooks, et al. is vastly different from the claimed method and fails to disclose numerous limitations of independent claim 37. First, Brooks, et al. completely fails to disclose the claimed “scavenging zone.” As noted above, the “scavenging zone” of the present claims is “immobilized” with a capture reagent (e.g., antibody) that is specific for the analyte (e.g., antigen). While the “contact region” of Brooks, et al. certainly contains antibodies specific for the analyte, they are bound to “test particles” that move through the membrane strip during testing and become bound within the detection region. Such “test particles” are more akin to the claimed “detection probes”, which also bind to the analyte to form complexes that flow through the membrane and bind with the capture reagent at the detection zone.<sup>1</sup> The differences noted above are not trivial, but fundamental to the entire operation of Brooks, et al. The emphasis of Brooks, et al. is to employ internal control particles that can *flow through the strip* to help account for any non-specific binding that may occur during performance of the assay. The present claims operate in exactly the opposite manner in that the scavenging zone contains a non-diffusively immobilized capture reagent that is able to “capture” a certain quantity of the analyte. If the capture reagent in the scavenging zone flowed through the

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<sup>1</sup> Of course, even if the “test particles” could somehow constitute the capture reagent of the scavenging zone, the claimed “detection probes” would then be missing from Brooks, et al. because the only remaining particles in Brooks, et al. – the “internal control particles” – do not include a binding member that is “specific” for the analyte as required by independent claim 37.

membrane in the same manner as the particles of Brooks, et al., the entire purpose of the scavenging zone would be eliminated as the analyte within the scavenging zone could then become bound within the detection zone.

Of course, Brooks, et al. fails to disclose other limitations of independent claim 37. For example, claim 37 requires that the device contains a separate sampling pad, conjugate pad, and porous membrane and that the scavenging zone is defined by the sampling pad, the detection probes are located on the conjugate pad, and the detection and calibration zones are defined by the porous membrane. Fig. 1 of the present invention, which is reproduced below, illustrates one embodiment of this configuration.



As shown, the sampling pad 17 defines the scavenging zone 35, the conjugate pad 22 contains detection probes (not shown), and the porous membrane 23 defines the detection zone 31 and the calibration zone 32. Such a configuration provides a variety of benefits, including the ability to remove a certain portion of the analyte at the location of sample application. Nowhere does Brooks, et al. disclose an assay device having the configuration of independent claim 37.

The Office Action attempted to cure the deficiencies noted above by combining Brooks, et al. with Buck. Applicants respectfully submit, however, that this combination is misplaced due to the vastly different nature of the systems of these references. The analyte modulating zone of Buck, for instance, does not take in account the non-specific

binding that Brooks et al. is concerned with and, therefore, would impact the operation of Brooks et al. and the quantitative calculation of the analyte.

In any event, the combination still fails to disclose certain requirements of the present claims, such as a scavenging zone defined by a sampling pad, detection probes located on the conjugate pad, and detection and calibration zones defined by the porous membrane. Example 1 of Buck, et al. is illustrative of this point. In this Example, a pregnancy test strip was first obtained from SA Scientific that contained a nitrocellulose membrane and a glass fiber conjugate pad containing gold particles conjugated with anti- $\beta$  hCG antibody. Once obtained, the conjugate pad was removed with a razor blade so that a portion of the nitrocellulose membrane corresponding to space 20 in Fig. 1 could be applied with anti- $\beta$  hCG capture antibody. The conjugate pad was then applied with latex beads conjugated with  $\alpha$ -region hCG and placed back into its original position. As noted, however, the test strip lacked a separate sampling pad on which a scavenging zone was defined. The recent Office Action argues that the wicking pad 14 of Fig. 1 is akin to the sampling pad. Even if true, however, Buck, et al. simply does not disclose the use of separate sampling and conjugate pads on which a capture reagent and detection/calibration probes are respectively located. Thus, for at least the reasons indicated above, Applicants respectfully submit that the presently claims patentably define over the cited references, taken singularly or in any proper combination.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited

Appl. No. 10/718,996  
Amdt. dated Apr. 14, 2008  
Reply to Office Action of Nov. 13, 2007

and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit  
Account No. 04-1403.

Respectfully requested,

DORITY & MANNING, P.A.

4/14/08  
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